K140711

JUN 20 2014

Paragon BioTeck, Inc.

510(k) Summary or 510(k) Statement

Contact Details

Applicant Name: Paragon BioTeck, Inc.

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Lauren M-C Bluett

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Date Prepared: 13JUN2014

Device Name

Trade Name: (1) Comfortear® Lacrisolve™ Absorbable Punctum Plug

(2) Lacrisolve™ Absorbable Punctum Plug

(3) Comfortear® Lacrisolve™ Punctum Plug

(4) Lacrisolve™ Punctum Plug

Common Name: Intracanalicular Plug/Punctum Plug

Classification Name: Plug, Punctal

Legally Marketed Predicate Device(s)

The Comfortear® Lacrisolve™ Absorbable Punctum Plugs have similar technological characteristics as the predicate devices. Like the currently marketed Opaque Herrick Lacrimal Plug (K030300), and the Temporary Intracanalicular Collagen Implant (K890919) the modified device is a sterile, monofilament synthetic absorbable suture material at the same or similar diameters and at the same or similar lengths.

510(k) Number	Product Code	Trade Name	Applicant
K030300	LZU	DISSOLVABLE OPAQUE HERRICK LACRIMAL PLUG	LACRIMEDICS, INC.
K890919	LZU	TEMPORARY INTRACANALICULAR COLLAGEN IMPLANT	EAGLE VISION, INC.

Device Description

Comfortear® Lacrisolve™ Absorbable Punctum Plugs are intended to temporarily block tear drainage by occlusion of the canaliculus. The plug is supplied in various sizes ranging from 0.2mm to 0.5mm in diameter and has a length of approximately 1.75mm, see table below. The plug is dyed (D&C Violet No. 2). Comfortear® Lacrisolve™ Absorbable Punctum Plugs are composed of the following absorbable suture materials: polydioxanone (PDO).

Size (mm)	0.2	0.3	0.4	0.5
Length (mm)	1.75	1.75	1.75	1.75

The design features of the Comfortear® Lacrisolve™ Absorbable Punctum Plugs raise no new issues of safety or effectiveness. Comfortear® Lacrisolve™ Absorbable Punctum Plugs consist of a length of monofilament synthetic absorbable suture material. The

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Comfortear® Lacrisolve™ Absorbable Punctum Plugs are provided sterile. The Comfortear® Lacrisolve™ Absorbable Punctum Plugs are available in various sizes to accommodate different patient physiologies and achieve occlusion of the canaliculus (or punctum). Two plugs are included in each package and there is one package in each box. This device is sub-punctal, to limit contact and possible irritation to the eye.

Comfortear® Lacrisolve™ Absorbable Punctum Plugs are contraindicated for use in patients with known sensitivity to any one of the materials that comprise the device, infectious conjunctivitis, dacrocycstitis, inflammation of the eyelid, infected eyes, or epiphora.

Intended Use/Indications for use

The Comfortear® Lacrisolve™ Absorbable Punctum Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Determine the potential effectiveness of permanent occlusion,
- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye, and
- Temporarily treat dry eye after ocular surgery.

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Substantial Equivalence Comparison

Elements	DISSOLVABLE OPAQUE HERRICK LACRIMAL PLUG (K030300)	Comfortear® Lacrisolve™ Absorbable Punctum Plug	TEMPORARY INTRACANALICULAR COLLAGEN IMPLANT (K890919)
Indications	Dissolvable Opaque Herrick Lacrimal Plug® may be used: • As a diagnostic aid to determine the potential effectiveness of Occlusion Therapy with non-dissolvable plugs. • To temporarily enhance the efficacy of topical medications or ocular lubricants. • After ocular surgery to prevent complications due to dry eyes. • To evaluate treatment of ocular dryness secondary to contact lens use. • In the treatment of Dry Eye Syndrome and the dry eye components of varying Ocular Surface Diseases.	The Comfortear® Lacrisolve™ Absorbable Punctum Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to: • Determine the potential effectiveness of permanent occlusion, • Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases, • Temporarily enhance the efficacy of topical medications or ocular lubricants, • Temporarily treat contact lens intolerance secondary to dry eye, and • Temporarily treat dry eye after ocular surgery.	Ideal for: • Treatment of post lasik induced dry eye • Treatment of seasonal dry eye • Retention of ocular medication

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Design Elements			
Intracanalicular Punctum Plug	Yes	Yes	Yes
Intended Duration	Approximately 180 days	Approximately 180 days	60-180 days
Material	A copolymer of L-lactide and ε-caprolactone (PCL) or Polydioxanone (PDO) or glycolic acid & trimethylene carbonate copolymer	Polydioxanone (PDO)	Polycaprolactone (PCL)
Color Additive	D&C Violet No. 2	D&C Violet No. 2	N/A
Packaging	Tyvek/Poly pouch	Tyvek/Poly pouch	Tyvek/Poly pouch
Method of Insertion	Forceps	Forceps	Forceps
Method of Removal	Dissolution, Saline irrigation, or Lacrimal probe	Dissolution, Saline irrigation, or Lacrimal probe	Dissolution, Saline irrigation, or Lacrimal probe
Method of Sterilization	EtO Sterilization (EO)	EtO Sterilization (EO)	Gamma Irradiation
Available Sizes	0.4mm, 0.5mm	0.2mm, 0.3mm, 0.4mm, 0.5mm	0.2mm, 0.3mm, 0.4mm

Similarities: The indications for use of the Comfortear® Lacrisolve™ Absorbable Punctum Plug and the predicate devices are very similar. The wording is different, but all the same situations are covered by the indications for use. In addition, most of the design elements are identical: type of plug, intended duration, suture material, color additive, packaging, method of insertion, method of removal, method of sterilization, and available sizes.

Differences: The only differences are that one (K030300) predicate submission covers punctum plugs made of three different suture materials and the current submission covers only one of those suture materials.

Based on the comparison tables above, the Comfortear® Lacrisolve™ Absorbable Punctum Plug is substantially equivalent to the predicate products.

Testing

Comfortear® Lacrisolve™ Absorbable Punctum Plugs will be sterilized by ethylene oxide sterilization. The program used to validate the sterilization process complies with the EN ISO 11135-1:2007 Medical Devices – Validation and routine control of ethylene oxide sterilization. A half cycle was utilized to validate the ethylene oxide sterilization process.

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This process is validated to ensure that a sterility assurance level of 10^{-6} or better is achieved. Each sterilization run is monitored by an independent accredited laboratory.

The levels of ethylene oxide sterilization residuals that remain on Comfortear® Lacrisolve™ Absorbable Punctum Plugs will comply with the requirements of ANSI/AAMI/ISO 10993-7:2008(R)2012 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals.

During testing for EO and ECH residuals, the results fell far below the standard stated above.

In order to ensure consistency of product, an upper control limit was set that is more indicative of routine testing. The calculation of +3 standard deviations from the data could not be calculated based on the results being the same number for all lots tested; therefore a value of three (3) times the measured value is the upper limit. This number remains well below the ISO standards acceptable for the device. The lower limit is zero (0) for all values. All routine testing shall be trended as well to ensure consistency of sterilization.

Total Extractable Residual Upper Limits

Extraction (hrs)	EO	ECH
	Total mg/device	Total mg/device
Prolonged or Lifetime	0.003	0.021

Limulus Amebocyte Lysate (LAL) testing was performed to assess the level of endotoxins on the product. (The Bacterial Endotoxins Test, or *Limulus* Amebocyte Lysate (LAL) test, is an *in vitro* assay to detect and quantify bacterial endotoxin, a component of the cell wall of Gram negative bacteria. Standard controls and a positive product control (PPC) demonstrate a compliant assay. A PPC recovery within the 50%-200% range indicates that the test solution is free of interfering factors given the specific conditions of the test. If applicable, dilutions are calculated into the reported endotoxin level.) The testing was conducted in accordance with the following regulatory documents: ANSI/AAMI ST72:2011, USP <161>, USP <85>, EP 2.6.14, and JP 4.01. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

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Kinetic Turbidimetric Results:

Test Article	Quantity	Extraction Volume	Detected Endotoxin	PPC Recovery
1	2 (pooled)	7.5 mL/device	<0.00500 EU/mL or <0.0375 EU/device	147%
2	2 (pooled)	7.5 mL/device	<0.00500 EU/mL or <0.0375 EU/device	124%
3	2 (pooled)	7.5 mL/device	<0.00500 EU/mL or <0.0375 EU/device	125%

Endotoxin Limit: For medical devices, the endotoxin limit is not more than 20.0 EU/device. For medical devices in contact with cerebrospinal fluid the limit is not more than 2.15 EU/device.

Preparation: The extraction was performed by immersing the test article in endotoxin free water and placing it on an orbital shaker in an incubator for 40-60 minutes at 37-40°C.

Test Procedure: The assay was performed at a sensitivity of 0.005EU/mL using Charles River reagents. For valid results, the combination of lysate and test solution was verified to be within 6-8 pH units.

Based on the testing above, the device has passed all LAL testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2014

Paragon Bio Teck, Inc.
Ms. Lauren McBluett
Director of Quality Assurance
4640 SW Macadam, Suite 80
Portland, OR 97239

Re: K140711
Trade/Device Name: Comfortear® Lacrisolve™ Absorbable Punctum Plug
Regulation Number: (Unclassified)
Regulation Name: (Unclassified)
Regulatory Class: Unclassified
Product Code: LZU
Dated: May 29, 2014
Received: May 30, 2014

Dear Ms. McBluett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140711

Device Name
Comfortear® Lacrisolve™ Absorbable Punctum Plug

Indications for Use *(Describe)*
The Comfortear® Lacrisolve™ Absorbable Punctum Plugs are intended to temporarily block tear drainage by the occlusion of the canaliculus in order to:

- Determine the potential effectiveness of a permanent occlusion,
- Temporarily treat dry eye syndrome, and the dry eye components of various ocular surface diseases,
- Temporarily enhance the efficacy of topical medications or ocular lubricants,
- Temporarily treat contact lens intolerance secondary to dry eye, and
- Temporarily treat dry eye after ocular surgery

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Susanna W. Jones -S
2014.06.17 14:10:07 -04'00'

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